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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
30775-701.403

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on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/072,010	October 25, 2001
First Named Inventor	
Jonathan W. Nyce	
Art Unit	**Examiner**
1617	San Ming R. Hui

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided, not including signature page.

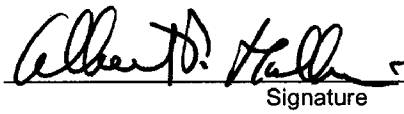
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 25,227

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

Al Halluin
Typed or printed name

(650) 493-9300
Telephone Number

May 31, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of ____ forms are submitted.

This collection of information is required by 35 CFR 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONICALLY FILED MAY 31, 2006

Attorney Docket No. 30775-701.403

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Confirmation No.: 5176
Applicant: Jonathan W. Nyce	Group Art Unit: 1617
Serial No.: 10/072,010	Examiner: San Ming R. Hui
Filed: October 25, 2001	Customer No. 021971
Title: COMPOSITIONS FOR TREATMENT OF ASTHMA OR BRONCHOCONSTRICTION (As Amended)	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL CONFERENCE BRIEF

Introductory Comments

This brief is responsive to the Final Office Action mailed March 2, 2006, and as such we have enclosed a Pre-Appeal Conference Brief and a Notice of Appeal for the above-referenced application. Payment of the $250.00 fee (small entity) for the Notice of Appeal has been authorized through electronic filing. Reconsideration is respectfully requested. Please reconsider the rejections of record in the above-referenced application as follows:

Summary of Claims

Claims 1-159, 163-164, and 166-186 stand cancelled. Claims 160-162, 165, and 187-190 are pending and for the convenience of the Review Panel they are set forth in Attachment A.

Summary of Claimed Subject Matter

The claims of the above-referenced application relate to a pharmaceutical composition comprising a DHEA type compound or salt thereof and a carrier, where the pharmaceutical composition comprises particles of about 1.0 μm to about 5 μm or the pharmaceutical composition comprises particles of about 15 μm to about 500 μm in size for treatment of bronchoconstriction, lung inflammation, lung allergy, or asthma.

REMARKS

This Pre-Appeal Brief is in response to the Examiner's Final Office Action mailed March 2, 2006. Even though new grounds for rejection were made, the Examiner made this action final.

Claim Rejections Under 35 U.S.C. 103(a)

A. The Examiner rejected claims 160-162 under 35 U.S.C. 103(a) as being unpatentable over Prendergast (4,956,355) in view of Lieberman et al. (Pharmaceutical Dosage Forms, page 110, of record) and "Remington: The Science and Practice of Pharmacy", 17th Ed, by Alfonso R. Gennaro, 1985, page 1505 (PTO-892).

The Examiner stated that, "Prendergast discloses ... enteral, parentral, injectable, topical, inhalations or nasal inhalation ...." The Examiner further stated that, "Prendergast does not expressly disclose the particular ranges of particle size herein, about 1.0-5 μm in size." The Examiner stated that Remington teaches that, "... the optimum particle size for preparation into the pulmonary cavity is of the order of ½ to 7μm ...." The Examiner stated that Lieberman et al. teaches that, "a skilled artisan in pharmaceutical science would clearly knowledge that the granulation, determination of size, or size reduction of a solid pharmaceutical formulation, e.g., in nasal inhalation formulation, have several benefits, for example as taught in a text book ...." The Examiner further stated that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine and granulate the dehydroepiandrosterone sulfate particles in range of size herein for nasal inhalation. Applicant traverses the rejection for the following reasons.

The Examiner has cited Lieberman out of context. Lieberman states that, "Size reduction, as it applies to tablet production ...." The size of the drug in a tablet is different from the size of the particle in inhalation.

The basis of every practical application starts from a text book. Every scientific application has a theory behind it, which would have been explained at great length in a text book but that does not enable a person of ordinary skill in the art to come up with specific formulations of drugs for the treatments of specific disorders in humans. Formulation of a drug especially for inhalation is a

complicated assemblage of various ingredients, parameters and optimization which cannot be obtained from a text book.

Applicant reiterates the statements made in a response to the office action[1] that while the primary references cited include many modes of administrations this alone does not render the claimed compositions as being unpatentable. It is possible for a prior art reference to include a wide variety of species, but not to disclose a particular subject matter, as here claimed. See In re Ruschig (CCPA 1967) 379 F2d 990, 154 USPQ 118. The legal question is: Whether or not it can be fairly and reasonably said that one of ordinary skill in this art through a reading of the entire reference has constructive possession of the claimed composition itself, as opposed to the possession of mere language which somehow embraces the name of what may be claimed. See In re Lavisi et al., 144 USPQ 646 at page 650.

Firstly, Prendergast intends to use dehydroepiandrosterones (DHEA type compounds) for retroviral infections where it is important that the DHEA type compound be administered such that it is present systemically throughout the body. Secondly, Prendergast gives a "laundry list" of the routes of administration, see column 5, lines 63. In the examples, Prendergast discloses an oral formulation of dehydroepiandrosterone sulphate enclosed in a capsule. The question is: Upon reading Prendergast, why would a person of ordinary skill in the art look for an inhalation formulation of dehydroepiandrosterones with a specific particle size and use it for treating respiratory diseases as a localized non-systemic treatment[2]? Why would one skilled in the art go to textbooks for inhalation formulations? Meanwhile, Remington is a text book on science and practice of pharmacy which discloses a list of devices, particles sizes, reagents, solvents, and formulations for all sorts of deliveries of pharmaceuticals, involving oral administration such as shown in Prendergast. It is not possible for a person of ordinary skill in the art to pick and choose from thousands of possible combinations of not just the formulation but also the route of administrations in a text book and come up with an inhalable composition for treating disorders such as bronchoconstriction, lung inflammation, lung allergy, or asthma. Prendergast, Lieberman and

1 On page 7-8 in the response dated Dec. 1, 2005 to the Office action dated Sep. 2, 2005.
2 See Cynthia Robinson's declaration, attached to response dated March 14, 2005 to the office action dated Dec. 14, 2004.

Remington do not motivate a person of ordinary skill in the art with a reasonable expectation of success to choose a certain particle size for DHEA and its derivatives for inhalation.

Pursuant to MPEP 2141.03, "Factors that may be considered in determining level of ordinary skill in the art include (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984). "The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984).

Applicant asserts that formulation of inhalable drugs is a sophisticated and unpredictable technology and there are various types of problems that are encountered in formulating an inhalable drug, including choosing a particle size for a drug, the compatibility of the particle size with the delivery device and the suitability of the particle size and the delivery device in the treatment of a respiratory disease. A person of ordinary skill in the art cannot formulate a drug for inhalation based on a disclosure in a text book.

Due to lack of suggestion or motivation in the cited references with a reasonable expectation of success, the rejection under 35 U.S.C. 103(a) is in error and should be withdrawn.

B. The Examiner rejected claims 187-189 under 35 U.S.C. 103(a) as being unpatentable over Prendergast, Lieberman et al. and Remington as applied to claims 160-162, 165 above, and further in view of Kelly and Hill, Chapter 24; Asthma in Pharmacotherapy – A Pathophysiologic Approach, 2nd ed., 1992, pages 408-449 by Elsevier.

The Examiner stated that, "Kelly and Hill teaches the devices for delivering therapeutic aerosols generate particles with aerodynamic diameters from 0.5 to 35μm in diameter ...." Applicant points out to the Examiner that even though Kelly and Hill is the new ground of rejection, the office action has been made final. Applicant asserts that along with the same reasons as provided earlier, Kelly and Hill also do not suggest or motivate with a reasonable expectation of success to formulate an inhalable DHEA formulation with a particle size of 15 μm to 500 μm.

Due to lack of suggestion or motivation in the cited references with a reasonable expectation of success, the rejection under 35 U.S.C. 103(a) is in error and should be withdrawn.

C. The Examiner rejected claims 160-162, 165 and 187-190 under 35 U.S.C. 103(a) as being unpatentable over Nyce (5,527,789, of record) in view of Lieberman et al., "Remington: The Science and Practice of Pharmacy", and Kelly and Hill.

The Examiner stated that, "Nyce also discloses the instant forms of the formulation, e.g., nasal spray (see col. 7 line 17) oral, rectal, topical, transdermal, nasal, or parenteral, including injectable ... The cited prior art does not expressly disclose the particular particles of the active agents having size herein, about 1-5 μm or about 15-500 μm in size."

For the same reasons as provided earlier Applicant asserts that Nyce gives a "laundry list" of the routes of administration and Lieberman, Remington and Kelly and Hill are text books which contain theoretical disclosure on devices, particles sizes, reagents, and formulations. It is not possible for a person of ordinary skill in the art to choose from thousands of possible combinations of not just the formulation but also the route of administrations and come up with an inhalable composition for treating disorders such as bronchoconstriction, lung inflammation, lung allergy, or asthma. Nyce, Lieberman, Remington and Kelly and Hill do not suggest or motivate a person of ordinary skill in the art with a reasonable expectation of success to choose a certain particle size for DHEA and use it for inhalation.

Due to lack of suggestion or motivation in the cited references with a reasonable expectation of success, the rejection under 35 U.S.C. 103(a) is in error and should be withdrawn.

CONCLUSION

Applicant respectfully solicits the panel of Examiners to grant a finding of allowance on the existing claims and expedite issuance of this patent application. Should the panel have any questions, the panel is encouraged to telephone the undersigned.

The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 30775-701.403).

Respectfully submitted,

Date: May 31, 2006 By: 

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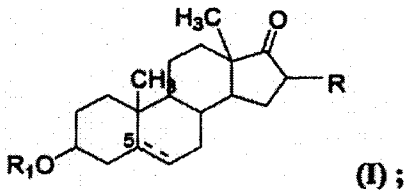
Attachment A

1-159. (Cancelled)

160. (Previously Presented) A pharmaceutical composition, comprising a carrier and an amount of an active agent effective for treatment of bronchoconstriction, lung inflammation, lung allergy, or asthma selected from dehydroepiandrosterone, or pharmaceutically or veterinarily acceptable salts thereof, the dehydroepiandrosterone having the chemical formula



(I);

wherein the broken line represents a single or double bond; R is hydrogen or halogen; the H at position 5 is present in the alpha or beta configuration or the compound of chemical formula I comprises a racemic mixture of both configurations; and R_1 is SO_2OM, wherein M is H,

wherein the pharmaceutical composition comprises particles of about 1.0 μm to about 5 μm in size.

161. (Previously Presented) The pharmaceutical composition of claim 160, wherein said active agent is dehydroepiandrosteronesulfate.

162. (Previously Presented) The pharmaceutical composition of claim 160, which is an inhalable or nasal formulation.

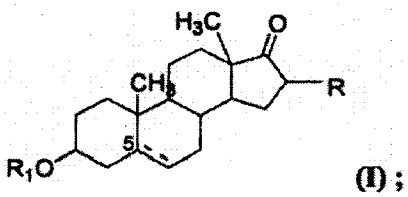
163. (Cancelled)

164. (Cancelled)

165. (Previously Presented) The pharmaceutical composition of claim 160, further comprising an amount of ubiquinone (CoQn, wherein n=1 to 12) effective to reduce adenosine depletion.

166 - 186. (Cancelled)

187. (Previously Presented) A pharmaceutical composition, comprising a carrier and an amount of an active agent effective for treatment of bronchoconstriction, lung inflammation, lung allergy, or asthma selected from dehydroepiandrosterone, or pharmaceutically or veterinarily acceptable salts thereof, the dehydroepiandrosterone having the chemical formula



(I);

wherein the broken line represents a single or double bond; R is hydrogen or halogen; the H at position 5 is present in the alpha or beta configuration or the compound of chemical formula I comprises a racemic mixture of both configurations; and R_1 is SO_2OM, wherein M is H

wherein the pharmaceutical composition comprises particles about 15 μm to about *500* μm in size.

188. (Previously Presented) The pharmaceutical composition of claim 187, wherein said active agent is dehydroepiandrosteronesulfate.

189. (Previously Presented) The pharmaceutical composition of claim 187, which is an inhalable or nasal formulation.

190. (Previously Presented) The pharmaceutical composition of claim 187, further comprising an amount of ubiquinone (CoQn, wherein n=1 to 12) effective to reduce adenosine depletion in an animal tissue.